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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/694,235
Filing Date: October 27, 2003
Appellant(s): RACZ ET AL.

Alexander T. Stein, PhD (Registration No. 66,296)
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 21, 2011 appealing from the Office action mailed August 19, 2011.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1, 3-9, 12-23, 25-32, and 34-38 are pending.

Claims 7, 13, 19, 22, and 26 are withdrawn from consideration.

Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 34-38 stand finally rejected and are the subject of this appeal.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office

action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,871,470	McWha	2-1999
5,250,035	SMITH et al	10-1993
2005/0070881	GRIBBONS et al	3-2005
2004/0236307	KLEIN	11-2004

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 8, 9, 12, 14-18, 20, 21, 23, 25, 27-32, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,871,470 to McWha in view of USPN 5,250,035 to Smith et al.

Regarding claims 1-6, 8, 9, 12, 14, 15, 29, and 32, McWha teaches a flexible spinal needle catheter assembly (10) comprising: a flexible needle catheter (12), said flexible needle catheter defining a hollow bore (14) for conveying medicating agent therethrough, said bore extending through a length of said flexible needle catheter, said flexible needle catheter having a proximal end which defines a leading edge (16; Fig. 2); a support needle releasably secured to said flexible needle catheter (22), said support needle being disposed within said hollow bore of said flexible needle catheter (Fig. 2), said support needle having a first end which defines a pencil point, non-cutting piercing point (27) configured for penetrating the dura mater of a patient (46; Fig. 6), said

support needle having an outside diameter sized so that upon withdrawal of the flexible spinal needle catheter assembly from a dura mater of a spine of a patient, subsequent to an insertion of said assembly through the dura mater, a puncture opening produced by said insertion is of dimensions which permit the dura mater substantially to reseal said puncture opening formerly occupied by the flexible spinal needle assembly within said dura mater (The examiner notes that the phrase beginning with “sized so that” has been interpreted as functional language and as such, the prior art need be only capable of performing the function above, and based on the size chosen, McWha would have been capable of performing the above function.), said support needle defining a hollow lumen (24) which extends along a length of said support needle and an opening (29), defined proximate said first end, which communicates the environment with said lumen, said support needle being positionable (this term has been interpreted to mean “capable of being positioned” and as such the device of the prior art need only have the structure capable of performing the following function(s)) in two conditions relative to said flexible needle catheter; in a first condition said support needle being positioned with said first end being positioned outside of said bore of said flexible needle catheter, said non-cutting piercing point and said opening being positioned outside of said bore (Fig. 3), the opening being positioned contiguous to the leading edge of the flexible needle catheter (the examiner notes that the flexible needle catheter is extended from the position shown in Figure 2 to that shown in Figure 3 and as such, as the opening passes the leading edge, they are contiguous) and in a second condition said support needle being removed from within said hollow bore of said flexible needle catheter (Fig.

1 shows the components are separable and may be located apart from one another either before or after use), and a solid stylet (25), releasably secured within said lumen, said stylet being positioned in a first condition to preclude access from the environment to said lumen through said opening (Col. 5, lines 61-65). Furthermore, McWha teaches that said leading edge of said flexible needle catheter is positioned proximate said pencil point tip (Fig. 3), that the flexible needle assembly has a leading edge configured and arranged to provide a feedback signal to indicate dural puncture (Col. 2, lines 1-8), that a rear end of said support needle carries a support hub (30) having a first attach structure (33); and a proximal end of said flexible needle carries a flexible needle hub (20) having a second attach structure (32) configured to removably attach to the first attach structure carried by said support hub (by rotation), that the first and second attach structures comprise a luer lock type connection (17; Fig. 2), and that the flexible needle hub is configured for substantially unobtrusive attachment to a patient's skin by way of an intermediary adhesive element (the examiner notes that the device of McWha is capable of being taped to a patient's skin). Additionally, McWha teaches that a rear end of said support needle carries a support hub (30); and a proximal end of said flexible needle carries a flexible needle hub (20) having a detach structure (32) configured to detach the flexible needle hub from the support hub (by rotation), that a proximal end of said flexible needle carries a flexible needle hub (20); and a rear end of said support needle carries a support hub (30) having a detach structure (33) configured to detach the flexible needle hub from the support hub, that said flexible needle comprises a force absorbing structure to prevent kinking when the flexible needle is

overly flexed (outer hub sleeve, see Figure below), and that said force absorbing structure comprises a flexible kink sleeve disposed on a portion thereof (see Figure below). McWha further teaches that said stylet is slidably mounted in said support needle (Fig. 1), that said first end of said flexible needle catheter is tapered into a curve to blend smoothly into the outer surface of said support needle (Fig. 4A), and that said flexible needle catheter is disposed on an outer surface of said support needle (Fig. 2).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claims 16-18, 20, 21, 23, and 35, McWha teaches a flexible spinal needle assembly (10) for inserting a distal end of a flexible spinal needle through dura mater into a spine of a patient, said flexible spinal needle assembly comprising: a flexible needle (12) having a bore through a length thereof; a support needle (22) having a proximal end (20) and a pencil point non-cutting piercing point at a distal end (27), said support needle being releasably secured to said flexible needle to resist relative motion between a distal end of said flexible needle and said pencil point non-cutting piercing point during insertion of said flexible spinal needle assembly into a patient (via threads 32, 33); wherein said flexible needle is carried exterior to said support needle to expose said non-cutting piercing point when said assembly is positioned for said

inserting (Fig. 3), and wherein said support needle is positionable (this term has been interpreted to mean "capable of being positioned" and as such the prior art need only disclose a structure capable of meeting the claimed limitations) in two conditions relative to said flexible needle; in a first condition said support needle is positioned with said bore of said flexible needle with said distal of end of said support needle being positioned outside of said internal bore of said flexible needle, said non-cutting piercing point and said opening being positioned outside of said bore (Fig. 3); and in a second condition said support needle being removed from within said bore of said flexible needle catheter (Fig. 1; see above note on claim 1). McWha further teaches that said flexible needle has an exterior diameter configured such that withdrawal of said flexible needle from said dura mater, subsequent to insertion of the flexible needle assembly therethrough, permits said dura mater substantially to reseal a space formerly occupied by said flexible needle, and a tip and a flexible needle body of said flexible needle are of substantial elongated extent to be further extendable into the dura mater upon extraction of said support needle (The examiner notes that the phrase beginning with “configured such that” has been interpreted as functional language and as such, the prior art need be only capable of performing the function above, and based on the size chosen, McWha would have been capable of performing the above function.), and that said proximal end of said support needle carries a support hub (30) having a first attach structure (33); a proximal end of said flexible needle carries a flexible needle hub (20) having a second attach structure (32) configured to interface in removable interference with said first attach structure carried by said support hub (via rotation). Furthermore,

McWha teaches a distal end of said assembly being constructed to provide a perceptible feedback signal when said distal end of said flexible needle penetrates said dura mater (Col. 2, lines 1-8), that the flexible needle hub further being configured for attachment to medical fluid transfer equipment having structure to form a luer lock type connection (17), and that said flexible needle comprises a kink sleeve disposed on a portion thereof, said kink sleeve configured to prevent kinking of said flexible needle when said flexible needle is extended beyond the substantial flexure point during use (outer hub sleeve; see Figure below).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claim 25, McWha teaches a flexible spinal needle (10) comprising: a support needle (22) having a pencil point, non-cutting piercing tip (27), said support needle defining an interior lumen and an opening (the lumen begins at opening 29), said opening communicating said interior lumen with the exterior of said support needle; a flexible needle body (12) comprising an elongated hollow tube, said flexible needle body configured to be removably (after use in the patient, the components are separable) and slidably mounted on an exterior of said support needle (Figs. 2 and 3); and a flexible kink sleeve (the examiner notes that all structures have some degree of flexibility and as

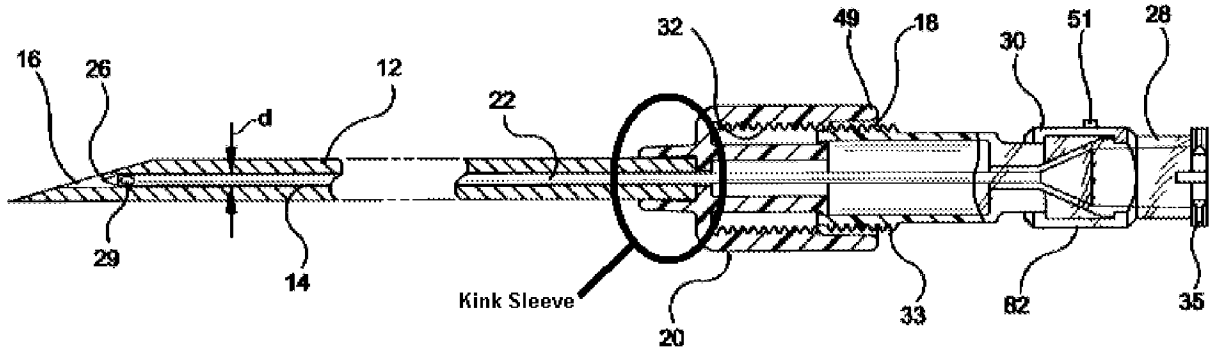
such has considered the kink sleeve of McWha to be flexible) disposed on a portion of said flexible needle body, said flexible kink sleeve being configured to prevent kinking of said flexible needle body, when said flexible needle body is bent beyond a flexible structural resilience thereof during use (outer hub sleeve; see Figure below), and wherein said support needle is positionable (this term has been interpreted to mean "capable of being positioned" and as such the prior art need only disclose a structure capable of meeting the claimed limitations) in two conditions relative to said flexible needle body; in a first condition said flexible needle body is mounted on said exterior of said support needle, said support needle being positioned with said first end of said support needle extending beyond said leading edge of said flexible needle body (Fig. 3); and in a second condition said support needle is removed from physical contact with said flexible needle body (Fig. 1; see above note on claim 1).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).

Regarding claim 27, McWha teaches a flexible spinal needle assembly (10) comprising: a support needle (22) comprising a first end defining a pencil point, non-cutting piercing point (27), and a hollow bore (24) with an opening (29) proximate said first end allowing access to said bore; and a flexible needle (12) slidably mounted on an

exterior portion of said support needle (Figs. 2 and 3) such that said first end of said support needle protrudes from said flexible needle exposing said pencil point, non-cutting piercing point and said opening, wherein said flexible needle has sufficient transverse flexibility to accommodate patient torso bending movement so as to substantially reduce a patient's awareness of the presence of the flexible needle (Fig. 3), said flexible needle defining a lumen therein for transporting a medicinal agent; wherein said support needle is positionable (this term has been interpreted to mean "capable of being positioned" and as such the prior art need only disclose a structure capable of meeting the claimed limitations) in two conditions relative to said flexible needle; in a first condition said support needle is positioned with said first end of said support needle extending beyond said leading edge of said flexible needle, said non-cutting piercing point and said opening being positioned beyond said leading edge (Fig. 3), the opening being contiguous to the leading edge (see note from claim 1); and in a second condition said support needle being removed from physical contact with said flexible needle (Fig. 1; see above note on claim 1).

However, McWha does not teach that the flexible needle catheter is comprised of a plastic. Smith et al teach a spinal needle catheter for administration of anesthetics and/or analgesics formed of a plastic (Abstract, Col. 1, lines 36-41). At the time of invention, it would have been obvious to one having ordinary skill in the art to form the flexible needle catheter of McWha using the plastic (for example, Teflon, a medical grade plastic) of Smith et al to take advantage of the more lubricious properties thereof (Col. 3, lines 19-33).



Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWha and Smith et al in view of USPGPub 2005/0070881 A1 to Gribbons et al.

McWha and Smith et al teach the limitations of claim 1 as taught above, but fail to teach or disclose a flat ribbon internal spring or metal band in the first end of the flexible needle catheter. Gribbons et al teach a flat metal ribbon or band (140) within the body of a catheter in order to provide support. It would have been obvious to one having ordinary skill in the art at the time the invention was made to add the flat metal band of Gribbons et al to the tip of the flexible needle catheter of McWha and Smith et al in order to further stabilize the tip to prevent bending during the insertion process.

Claims 34, 36, 37, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over McWha and Smith et al as applied to claims 1, 16, 25, and 27 above, and further in view of USPGPub 2004/0236307 A1 to Klein.

McWha and Smith et al do not disclose that the plane containing the leading edge of the outer flexible needle is positioned perpendicularly to a longitudinal axis of

the needle assembly. However, Klein teaches a cannula assembly having a flexible cannula and a stylet, wherein the stylet can be sharp-tipped (having a sloped leading edge) or blunt tipped (having a perpendicular leading edge) in the case that an incision already exists for insertion. At the time of invention, it would have been obvious to one having ordinary skill in the art to provide the device of McWha and Smith et al with a perpendicular or blunt leading edge on the flexible needle in order to follow a previous channel or incision into the patient and prevent additional tissue damage from a sharp point veering off course.

(10) Response to Argument

Regarding claim 1, and claims 3-6, 8, 9, 12, 14, 15, and 32 which stand or fall therewith, applicant has presented three distinct arguments.

In response to applicant's first argument, that one having ordinary skill in the art would not have combined the McWha and Smith et al references, the examiner disagrees. Although applicant has disclosed many reasons why McWha and Smith et al differ, applicant has failed to recognize the fact that the systems of the McWha and the Smith et al references are both drawn to epidural needles for insertion in the spinal column of a patient. As such, one having ordinary skill in the art, looking to make an improved spinal epidural catheter, would look to both the McWha and Smith et al references and, appreciating the benefits of various aspects thereof, combine their teachings to arrive at the claimed invention. Applicant appears to rely on the fact that McWha did not provide alternative materials for the composition of the catheter in their

specification. However, the absence of alternatives in the prior art does not preclude substitution should useful properties of another suitable material be recognized. The examiner additionally notes that applicant asserts that the references do not teach a flexible needle catheter having, in particular, “sufficient transverse flexibility to deform and accommodate patient motion after insertion”. The examiner disagrees, as applicant has not quantified the degree of flexibility and/or patient movement intended to be accommodated by the flexible needle catheter. As such, the examiner has considered any degree of “give" within the flexible needle catheter to be sufficient to fulfill the claim limitation. Finally, applicant asserts that the reason the examiner has provided for combination of the references is not the same as the claimed reason for the manufacture of the device from plastic, however the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's second argument, that the combination of McWha and Smith et al destroys the McWha reference, rendering it unsuitable for its intended purpose, the examiner disagrees. Applicant asserts that, because a device having “sufficient transverse flexibility to deform and accommodate patient motion after insertion” would not be able to neatly cut and penetrate the skin, that the device of McWha would be rendered useless. However, the examiner notes that, as noted above, any degree of "give" within the flexible needle catheter, just as there is "give" in a stainless steel catheter like that of McWha, will allow for some flexibility when the

patient moves. As such, a plastic catheter having a similar stiffness to that of the McWha reference would be capable of penetration through the skin of the patient.

In response to applicant's third argument, that the prior art combination fails to teach that the opening is positioned contiguous to the leading edge of the flexible needle catheter, the examiner again disagrees. The examiner has given the term "leading edge" its broadest reasonable interpretation to include the entire beveled edge of the flexible needle catheter. As such, the opening is contiguous with the leading edge. Applicant appears to be intending the leading edge to refer only to the insertion tip, but the examiner notes this is an unduly narrow interpretation of the claim language.

Regarding claim 16, and claims 17, 18, 20, 21, and 23 that stand or fall therewith, applicant presents two arguments.

Applicant's first argument provides the same grounds as applicant's first argument with respect to claim 1 above. The examiner maintains the grounds of rejection for the same reasons previously cited.

With respect to applicant's second argument, that McWha and Smith et al do not suggest that the flexible needle is used as a catheter, the examiner disagrees. Firstly, the flexible needle cannula of McWha as defined by the examiner, allows for the passage of the support needle therein, and therefore fulfills any and all limitations of the term "cannula" as understood in the art. It is noted that the features upon which applicant relies (i.e., that fluid must be delivered through the tube in order for it to function as a cannula) are not recited in the rejected claim(s). Although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding claim 25, applicant again presents three arguments, corresponding to the three arguments presented with respect to claim 1 above. The examiner relies on the above paragraphs for explanation of the maintenance of the rejection of claim 25.

Regarding claim 27, applicant again presents three arguments, corresponding to the three arguments presented with respect to claim 1 above. The examiner relies on the above paragraphs for explanation of the maintenance of the rejection of claim 27.

Regarding claim 28, applicant's arguments appear to be drawn to the combination of the material of Smith et al with the device of McWha, which was discussed with respect to the first and second arguments of claim 1 addressed above. The examiner draws attention to those paragraphs for explanation of the maintenance of the rejection of claim 28.

Regarding claim 29, applicant argues that McWha does not, as asserted by the examiner, show that the flexible needle catheter is curved to blend smoothly into the outer surface of said support catheter. However, the examiner notes that Figure 4A of McWha clearly shows a curved distal tip of the flexible needle catheter, which directly interfaces with the outer surface of the support catheter where it exits the opening, and

as such the interior surface of the flexible needle catheter blends smoothly with the exterior surface of the support catheter.

Regarding claim 36, applicant presents an argument corresponding to the third argument presented with respect to claim 1 above. The examiner relies on the above paragraph for explanation of the maintenance of the rejection of claim 36.

Regarding claim 30 and claim 31 which stands or falls therewith, applicant argues that Gribbons et al does not teach or suggest the deficiencies of Claim 1 asserted by applicant and therefore the rejection should be withdrawn. The examiner notes that there are no deficiencies in the rejection of claim 1 as argued above and as such, maintains the rejection of claim 30.

Regarding claim 34, applicant provides two distinct arguments.

Applicant's first argument is that Klein does not teach or suggest the deficiencies of Claim 1 asserted by applicant and therefore the rejection should be withdrawn. The examiner notes that there are no deficiencies in the rejection of claim 1 as argued above and as such, maintains the rejection as noted above.

Applicant's second argument, that the combination of McWha and Smith et al with Klein would render McWha unsatisfactory for its intended purpose, the examiner disagrees. The examiner notes that the insertion apparatus would still be capable of performing its intended functions should the leading edge be made perpendicular

because it would still be capable of guiding the support catheter to its intended destination through a preformed puncture as described by Klein. The examiner further notes that blunt tips are capable of penetrating tissue should enough force be provided.

Regarding claim 36, applicant provides two distinct arguments.

Applicant's first argument is that Klein does not teach or suggest the deficiencies of Claim 16 asserted by applicant and therefore the rejection should be withdrawn. The examiner notes that there are no deficiencies in the rejection of claim 16 as argued above and as such, maintains the rejection as noted above.

Applicant's second argument, is the same as that presented with respect to claim 34 above, and the examiner relies on the same rationale as described above.

Regarding claim 37, applicant provides two distinct arguments.

Applicant's first argument is that Klein does not teach or suggest the deficiencies of Claim 25 asserted by applicant and therefore the rejection should be withdrawn. The examiner notes that there are no deficiencies in the rejection of claim 25 as argued above and as such, maintains the rejection as noted above.

Applicant's second argument, is the same as that presented with respect to claims 34 and 36 above, and the examiner relies on the same rationale as described above.

Regarding claim 38, applicant provides two distinct arguments.

Applicant's first argument is that Klein does not teach or suggest the deficiencies of Claim 27 asserted by applicant and therefore the rejection should be withdrawn. The examiner notes that there are no deficiencies in the rejection of claim 27 as argued above and as such, maintains the rejection as noted above.

Applicant's second argument, is the same as that presented with respect to claims 34, 36, and 37 above, and the examiner relies on the same rationale as described above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/VICTORIA P CAMPBELL/

Primary Examiner, Art Unit 3763

Conferees:

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761